



**UNITED STATES DEPARTMENT OF COMMERCE
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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
| 08/238,080 | 05/03/94 | COLLINS | M 2583511 |

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| #13 | |
| ART UNIT | PAPER NUMBER |
| 1807 | |

DATE MAILED: 01/17/97

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

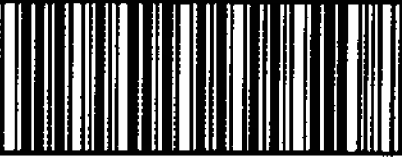
Office Action Summary

Application No.
08/238,080

Applicant(s)
Collins et al.

Examiner
Dianne Rees

Group Art Unit
1807



☒ Responsive to communication(s) filed on Oct 24, 1996

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 25-54 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 25-54 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit:

DETAILED ACTION

The Applicant's arguments filed 10/24/96 have been thoroughly reviewed. Rejections and/or objections not reiterated from the previous office action are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated. They constitute the complete set being presently applied to the present application. Response to applicant's arguments follow.

Claim Rejections - 35 USC § 112

1. Claims 51-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The following phrases render the claims vague and indefinite:

Claim 51 is indefinite in the recitation of "a second medium". Claim 27 does not recite a "first medium" so there is no context for the recitation of "a second medium" further it is unclear what the metes and bounds of the term "medium" is.

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Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 25-42, 44, and 48-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vary et al in view of Henson et al.. For reasons made of record in the previous office action.

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4. Claims 25-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vary et al in view of Henson et al. and further in view of Rabbani et al. For reasons made of record in the previous office action.

5. Claims 51-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vary et al in view of Henson et al.

Vary et al. In view of Hansen et al. Meets all of the limitations of the claims except for the teaching that the support, probe and bound target are contacted with a second medium (interpreted here to be a buffer solution) and that the target polynucleotide is released from the support into the second medium to be subsequently amplified. However, it would have been prima facie obvious to one of ordinary skill in the art at the time that the invention was made that the amplification process such as taught by Vary could perform equally well in solution as on the support and one of ordinary skill in the art, at the time that the invention was made, would have been modified to modify the method of Vary in view of Hansen to include such a release step, having a reasonable expectation of success in doing, and would have been motivated to do so for the expected benefit of utilizing the more rapid hybridization kinetics that occurs in solution to increase the efficiency of the PCR reaction steps of primer annealing.

6. No claims are allowed.

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Response to Applicant's arguments:

Discussion of rejections under 35 USC 112 second paragraph:

Rejections made previously under 35 USC 112 second paragraph are withdrawn in view of Applicant's amendments and arguments. However Applicant's amendments have necessitated a new grounds of rejection discussed above.

Discussion of rejections under 35 USC 103.

Applicant argues that years after the filing date of the present application, practitioners in the art found that PCR does not obviate the need for extensive purification of a product as promised and does not render it unnecessary to initially purify a sequence to be amplified and although they recognized the problem, these workers did not disclose or suggest Applicant's claimed method for solving it. Applicant further argues that the teachings of Hanson does not related at all to amplification methodology and so is not properly combined with Vary to overcome the teaching of these other references which relate directly to amplification methods. "Those with skill in the art cannot reasonably be expected to credit the teachings of Hanson for amplification methods and ignore the contrary teaching of Mullis and the other references discussed herein".

This argument is considered but is not found persuasive. It is true that Mullis teaches that it is not necessary that the sequence to be amplified by present initially in a pure form" . However this teaching of Mullis while directed to the steps that the ordinary artisan may skip (if willing to live with the consequences) does not prevent one or teach away from being more rigorous

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scientifically in purifying a target nucleic acid to be amplified. The question becomes whether performing such additional steps offer any *unexpected* improvements in the technique. As discussed in the previous office action, Vary teaches the advantages of solid supports in capturing a probe specifically and in high concentration with major other material not contributing to nonspecific signal. Henson teaches the separation of target nucleic acids bound to a solid support from a sample and the detection of the bound nucleic acids using a detectable label and that the order of binding a single stranded nucleic acid and the probe and the support may be varied according to experimental needs. This teaching applies generally to all methodology employing solid supports and is not rendered inapplicable to the instant claims simply because Hanson uses the methodology in a hybridization assay rather than in PCR. Since the rejection is applied in view of the teachings of the combined references, one cannot isolate the teaching of Henson from the teachings of Vary in consideration of the claims. Again, as stated in the previous action, the isolation of a target sequence from a complex biological sample as a means of providing increased sensitivity and lower background was known in the art at the time that the invention was made and although Mullis essentially teaches you what you can "get away with" to obtain desired results there is no teaching in Mullis that would lead one away from modifying the method to obtain the expected benefits of optimizing a technique as would be suggested by the combined teachings of Vary and Henson, and further in view of Rabbani. (In discussing Rabbani, again the applicant focuses on the teachings of Rabbani in isolation, the rejection was applied in view of the combined references and the fact that Rabbani does not teach amplification methods is not

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relevant to the fact that Rabbani provides teachings relevant to the use of multiple solid supports in general and the advantages that this provides one). Newly added claims 51-54, also, in view of the teachings of the art reflect, as well, optimization steps which the ordinary artisan would be motivated to perform.

4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire **THREE MONTHS** from the date of this action. In the event a first response is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than **SIX MONTHS** from the date of this final action.

Dianne Res
1/11/97

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SUPERVISORY PATENT EXAMINER
GROUP 1800
1/15/97